

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of: Srivastava, Pramod K.

Application No.: To Be Assigned  
(Continuation of Application No. 09/489,218)

Group Art Unit: To Be Assigned

Filed: On Even Date Herewith

Examiner: To Be Assigned

For: IMMUNOTHERAPEUTIC STRESS  
PROTEIN-PEPTIDE COMPLEXES  
AGAINST CANCER

Attorney Docket No.: 8449-183-999

**PRELIMINARY AMENDMENT UNDER 37 C.F.R. § 1.121**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Prior to examination of the above-captioned application, please enter the following amendments and consider the following remarks. Applicant submits herewith (a) a paragraph to be added to the specification, attached hereto as Exhibit A; and (b) a copy of the claims that will be pending upon entry of the present amendments, attached hereto as Exhibit B.

**IN THE SPECIFICATION:**

Please amend the specification as follows:

On page 1, please add the following paragraph on the line following the title of the specification:

This is a continuation of application no. 09/489,218 filed January 21, 2000, which is a continuation of application no. 09/061,365 filed April 16, 1998, now U.S. Patent No. 6,017,544, which is a division of application no. 08/315,892 filed September 30, 1994, now U.S. Patent No. 5,750,119, each of which is incorporated by reference herein in its entirety.

**IN THE CLAIMS**

Please amend the claims as follows:

Cancel claims 2 to 18 without prejudice.

Please add the following new claims:

19. (New) An isolated population of human stress protein-peptide complexes isolated from human tumor tissue excised from a human, wherein the peptides are noncovalently associated with the stress protein, and wherein the stress protein is human gp96.

20. (New) An isolated population of human stress protein-peptide complexes isolated from human tumor tissue excised from a human, wherein said population of complexes is a combination of Hsp70-peptide complexes, Hsp90-peptide complexes, and gp96-peptide complexes; and wherein the peptides are noncovalently associated with the stress protein.

21. (New) A composition comprising:

- (a) a therapeutically effective amount of purified human stress protein-peptide complexes isolated from human tumor tissue excised from a human, wherein the peptide is noncovalently associated with the stress protein, and wherein the stress protein is human gp96; and
- (b) a pharmaceutically acceptable carrier.

22. (New) A method for treating a mammal having a tumor sensitive to treatment with a human gp96-peptide complex comprising administering to the mammal a composition comprising:

- (a) an amount of purified immunogenic human gp96-peptide complexes isolated from human tumor tissue excised from a human, wherein the amount is sufficient to elicit an immune response against the tumor, wherein the peptides are noncovalently associated with the gp96; and
- (b) a pharmaceutically acceptable carrier.

23. (New) The method of claim 22 wherein the mammal is a human.

24. (New) The method of claim 23 wherein the mammal is the human from which the complexes are isolated.

25. (New) A method for treating a mammal having a tumor sensitive to treatment with a human gp96 peptide complex comprising:

- (a) isolating immunogenic human gp96-peptide complexes from human tumor tissue excised from a human, wherein the peptides are noncovalently associated with the gp96; and
- (b) administering a composition comprising an amount of the isolated complexes sufficient to elicit an immune response against the tumor, and a pharmaceutically acceptable carrier.

26. (New) The method of claim 25 wherein the mammal is a human.

27. (New) The method of claim 26 wherein the mammal is the human from which the complexes are isolated.

28. (New) A method for eliciting in a mammal an immune response against a tumor comprising administering to the mammal a composition comprising:

- (a) an amount of purified immunogenic human gp96-peptide complexes isolated from human tumor tissue excised from a human, wherein the amount is sufficient to elicit an immune response against the tumor, wherein the peptides are noncovalently associated with the gp96; and
- (b) a pharmaceutically acceptable carrier.

29. (New) The method of claim 28 wherein the mammal is a human.

30. (New) The method of claim 29 wherein the mammal is the human from which the complexes are isolated.

31. (New) The method of claim 23, 24, 26, 27, 29 or 30 wherein the complexes are administered to the human in an amount in the range of 1 to 1000 micrograms of complex per kg body weight of the human per administration.

32. (New) The method of claim 23, 24, 26, 27, 29 or 30 wherein the complexes are administered to the human in an amount in the range of 100 to 250 micrograms of complex per kg body weight of the human per administration.

#### REMARKS

New claims 19 to 32 have been added to more particularly point out and distinctly claim that which Applicant regards as the invention. The subject matter of the new claim recitations is fully supported in the specification. Support for the new claims is found in the specification as set forth in the chart below.

New Claims	Support is Specification
19 to 30	page 5, lines 19-31; page 8, lines 14-18 and 31-34; page 9, lines 9-11 page 10, lines 29-33
31, 32	page 11, lines 1-4

#### CONCLUSION

Applicant respectfully requests that the above-made amendments be entered and made of record in the instant application. An early allowance is earnestly requested.

Date November 14, 2001

Respectfully submitted, *Reg No. 31,232*  
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Enclosure